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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
SHAY, DAVID M				
ART UNIT		PAPER NUMBER		
3769				
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05/12/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/507,336

Applicant(s)

ANDERSON ET AL.

Examiner

david shay

Art Unit

3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 29, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,35,38,40,41,74,75 and 77-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,35,38,40,41,74,75 and 77-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GA-08)
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :November 4, 2008; November 26, 2008; and January 29, 2009.

Applicant argues that the examiner “makes the conclusory assertion that ‘Saul et al teaches a method such as claimed except for epicardial placement’” and asserts that this is not in compliance with MPEP § 2141, purportedly because there is no articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. The examiner respectfully notes that applicant has misconstrued the meaning of this passage. For applicant’s convenience, the examiner has reproduced the passage in context:

“Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”

Thus, as can be clearly seen, the “rational underpinning” is required in the explanation of the motivation for combination, not for the explanation of the teachings of the reference. If applicant believes that certain elements are lacking in a reference applied to the claims, the missing elements should simply be pointed out, rather than asserting a lack of “rational underpinning” for the determination that art reads on one or more aspects of the claim. Applicant’s attention is respectfully invited to MPEP § 706.02(j), which states that when rejecting claims under 35 U.S.C. 103(a), the examiner should set forth:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
 - (B) the difference or differences in the claim over the applied reference(s),
 - (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
 - (D) an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made.
- The rejection clearly states the teachings relied on, including citation of column and line

number (column 3, line 38 to column 4, line 17); the difference between the prior art and the applied reference(s) (e.g. “except epicardial placement”); the proposed modification (e.g. “to employ the epicardial placement of Chen et al in the device and method of Saul et al”); and an explanation as to why the invention It would have been obvious to the artisan of ordinary skill (e.g. “since the device and method of Chen et al is applicable to both epicardial and endocardial treatments”). Thus, clearly, the 35 U.S.C. 103(a) rejection is in compliance with the relevant sections of the MPEP, and is also otherwise proper.

At last, applicant then asserts that Saul et al fail to evidence specific elements of the claimed invention, which the examiner will now discuss. With regard to the limitation of “analyzing the temperature change over a first period of time to determine the temperature response of tissue at the tissue site”, since claims are to be given their broadest reasonable interpretation, the term analyze can be interpreted to mean to examine carefully and in detail so as to identify causes, key factors, possible results, etc. (dictionary.com, third sense), in Saul et al, the temperature change over a first period of time is analyzed to assure it reaches a point where the tissue is stunned.

With regard to characterizing the tissue based on the temperature response of the tissue, wherein the characterizing step consists of at least one of at least one of comparing the temperature response to with the temperature responses of other known tissue types and considering the input of at least one variable from the list of variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood, the examiner believes, in view of applicant's arguments, that the analysis of this portion of the claim language will be facilitated by parsing the limitation. The limitation relates to a further limitation of the step of characterizing the tissue. The further limitation can be at least one of 1) comparing the temperature response with temperature responses of other known tissue types of tissue; and 2) considering the input of at least one variable from a list of variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood. Therefore any reference that satisfies at least one of these limitations will supply the recited limitation in the claim. With regard to limitation 1), the term "known tissue types" is not classified in the originally filed disclosure, and thus the term is given its broadest reasonable interpretation. Thus these known tissue types would include known types of heart tissue; such as the different types of tissue at different locations in the heart. As a reading of the passage of Saul et al referred to in the office action will readily reveal, that reference teaches characterizing the temperature response of different known tissue types (e.g. known tissues in different locations in the heart) by observing the temporal extent of the lack of conduction of the tissue with respect to the temperature the tissue is subjected to. Additionally, with respect to this limitation, since one of ordinary skill in the art is a cardiac surgeon, one of ordinary skill in the art has a very high level of skill, the training for one of ordinary skill in the art would require not only 12 years of primary

and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a cardiac surgeon, one of ordinary skill in the art will also necessarily be very familiar with the conditions of heat flow in tissue and the factors that affect it. Clearly, the colder (or warmer) the medium surrounding the tissue to which is desired to be heated, the more (or less) heat will be required to heat the tissue throughout its entire extent to the desired temperature. Thus, with regard to limitation 2), taking into account the temperature of the blood, or as taught by Lesh, the thickness of the tissue that is desired to be heated, when characterizing the tissue (e.g. characterizing the amount of heat to be applied thereto to successfully ablate it), would be evident to one of ordinary skill in the art. Therefore, both limitations of the characterizing step are satisfied by the applied art, even though only one need be to satisfy the claim language at bar.

With regard to the limitation of determining an ablation time interval and a desired temperature, as also clearly set forth in the cited passage of Saul et al, once the tissue is characterized by determining the response to the 50 degree application (i.e. once the tissue has been characterized as either “still conducting” or “no longer conducting”), the ablation time and temperature was then determined (zero time interval for the “not conducting” tissue and 70 degrees C for 60 seconds for the “still conducting” tissue).

The argued limitations in claim 74 being roughly equivalent to and readable on the combination in essentially the same way, will not be discussed in further detail here. Further, the remainder of applicant’s arguments, excepting those directed to claims 80 and 81, are all predicated on the alleged deficiency of the base combination and the Saul et al reference, in

particular. However, as the combination is not deficient, as set forth above, these arguments are not convincing.

With respect to the arguments drawn to the use of cooling energy, He et al teach characterizing tissue. And while the bulk of the disclosure thereof is drawn to the use of RF energy to heat the tissue, the reference does specifically state that "It is important to note that the heart of the invention is the realization that the impedance characteristics of the ablation system and the capacitive nature of tissue can be exploited through the measurement of appropriate electrical parameters to estimate tissue temperature and lesion formation during the ablation procedure. The invention has been described in terms of ablation produced by an RF energy source, but it could be practiced as well with other sources, such as ultrasound and cryogenic, so long as electrical parameters related to the resistive and capacitive components of the tissue can be measured and correlated to tissue temperature and lesion formation." (column 9, line 58 to column 10, line 2). Thus this argument is also not convincing.

Claims 34-36, 38, and 74-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh. Saul et al teaches a method such as claimed except epicardial placement (see column 3, line 38 to column 4, line 17). Chen et al teaches the desirability of ablating on the epicardium or the endocardium. Lesh teaches the necessity of making transmural lesions to provide conduction block. It would have been obvious to, the artisan of ordinary skill to employ the epicardial placement of Chen et al in the device and method of Saul et al, since the device and method of Chen et al is applicable to both epicardial and endocardial treatments, or alternatively to use the low temperature and high temperature device and method of Saul et al in the device and method and device of Chen et al, since this

provides more reliable ablation of accessory pathways, as taught by Saul et al, and in either case to use an input of the tissue thickness, since this is required to determine the amount of energy required to produce a transmural lesion, without producing undesired damage in the heart, thus producing a device and method such as claimed.

Claims 40 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh, as applied to claims 34-36, 38, and 74-77 above, and further in view of Swanson et al. Swanson et al teaches the desirability of ablating on the epicardium and that less than half the total number of electrodes can be used. It would have been obvious to, the artisan of ordinary skill to employ the method and device of Swanson et al in the combined method and device of Saul et al, Chen et al, and Lesh, since this will allow greater control of the lesion size, thus producing a method and device such as claimed.

Claims 41 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh, as applied to claims 34-36, 38, and 74-77 above, and further in view of Ben Hain et al. Ben Hain teaches drawing tissue into a suction well prior to ablation. It would have been obvious to employ the device for and step of drawing the tissue desired to be ablated into suction surrounding the ablating elements since this allows the catheter to remain stable while the tissue is ablated, thus producing a method and device such as claimed.

Claims 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh as applied to claims 34-36, 38, and 74-77 above, and further in view of He et al. He et al teaches determining tissue parameters by cooling the tissue. It would have been obvious to employ the device for and step of cooling the tissue since this is

equivalent to the use of heating energy to do so, as taught by He et al, thus producing a method and device such as claimed.

Applicant's arguments filed January 29, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769